REMARKS

Rejection of Claims 1-4 under 35 USC §112, 1st paragraph

The Examiner has rejected Claims 1-4 as failing to comply with the written description requirement. The Examiner asserts that the terms "(C_3-C_8)-cycloalkanediyl" and "(C_9-C_{11})-heteroaryl ring" are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by these terms. Therefore, the Examiner concludes that the specification lacks adequate support for Claim 1. In addition, the Examiner asserts that Claims 1-4 fail to comply with the enablement requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the Examiner, Claims 1-4 are enabled for Ring A is (C_6)-cycloalkanediyl Applicant has amended Claims 1-4 so that Ring A is C6-cycloalkanediyl only. In addition, Applicant has amended Claims 1-4 so that these claims no longer recite "(C_9-C_{11})-heteroaryl ring". Applicants believe this amendment is sufficient to overcome the rejection of Claims 1-4. Applicant asserts these claims are now allowable in view of the amendment.

Rejection of Claims 13-19 under 35 USC §112, 1st paragraph

The Examiner rejected Claims 13-19 as failing to comply with the written description requirement. The Examiner asserts that the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Examiner cited MPEP 2164.01(a) and also cited the factors described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which are to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph. The Examiner then went on to assess the various factors. Applicants respectfully disagree with many of the assertions made by the Examiner.

As the CCPA observed with respect to 35 USC 112, first paragraph:

> "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject

> matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."

In re Marzocchi, 439 F.2d 220, 223; 169 USPQ 367, 369 (CCPA 1971). Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince a person of ordinary skill in the art of the asserted utility of the invention. In re Bundy, 642 F. 2d 430, 433; 209 USPQ 48, 51 (CCPA 1981). Furthermore, applicants submit that while the Law requires that the specification enable one skilled in the art to make and use the invention, the Law does not require exemplification, data, or tests. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. In re Marzocchi, supra. All that is required is that the specification teach how to make and use the invention without undue experimentation. Applicants submit that this has been done.

The specification of the instant application clearly states that the novel compounds of the present invention are useful for the treatment of the diseases and/or disorders recited in claims (page 10, line 34 through page 11, line 24). Furthermore, the specification states that the claimed compounds activate PPARalpha and PPARgamma (page 1, line 22), providing a disclosure of standard screens which can be used by art workers to demonstrate the PPAR effects of the claimed compounds (page 24, line 18 through page 32, line 22). There is no dispute that the specification provides an adequate disclosure of how to make the claimed compounds. The doses required for various modes of administration are specifically disclosed on page 13, line 26 through page 16, line 21. Specific daily doses are within the ability of one skilled in the art to determine without undue experimentation. The patient to be treated is defined on page 8, line 16.

Even if the PTO had met its initial burden, thereby shifting the burden to Applicants to offer rebuttal evidence, Applicants have already disclosed sufficient evidence to convince one of ordinary skill in the art of the credibility of the asserted utility of the claimed invention. Contrary to the Examiner's assertion on page 10 of the Office Action that "the specification has no working examples, such as *in vivo* or *in vitro* studies...", Applicants do disclose in vitro test data to demonstrate PPAR activity of certain compounds within the scope of Claim 1 in Table I (page 28) and there is ample support in the literature for Applicant's assertion that compounds having PPAR activity would be efficacious in treating the diseases and/or conditions recited in Claims 13-19. See for example, Berger et al.

(Annu. Rev. Med. 2002, 53:409-35; submitted with Applicant's IDS) wherein it is stated at the bottom of page 409: "[r]ecently, it has been demonstrated that the PPARs are the primary targets of numerous classes of synthetic compounds used in the successful treatment of diabetes and dyslipidemia".

The Examiner states at the bottom of page 9 of the Office Action: "[a]dded to the unpredictability of the art itself is the question whether without in vitro activity data, population data, and similar biological data demonstrating the efficacy of the compound of formula (I) against fatty acid metabolism, insulin resistance, diabetes mellitus, dyslipidemia, squelae, and metabolic syndrome diseases that the present invention could be reliably and predictably extrapolated to in vivo activity in patents with all types of fatty acid metabolism, insulin resistance, diabetes mellitus, dyslipidemia, squelae, and metabolic syndrome diseases claimed. There is no absolute predictability, even in view of the high level of skill in the art". In reply, Applicants contend that the Examiner is confusing the requirements for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. See In re Brana, supra. at 1442, quoting Scott v. Finney, 34 F.3d 1058 1063, 32 USPQ2d 1115, 1120 (CAFC 1994). Furthermore, the fact that syntheses would have to be carried out and bioassays conducted in order to determine the level of activity of a given compound within the scope of the claims does not constitute "undue experimentation," particularly in an art where the level of skill is so high. In re Wands, 8 USPQ2d 1400 (CAFC 1988).

The Examiner has presented no evidence whatsoever why one of ordinary skill in the art would doubt the objective truth of the methods described and claimed (i.e. Claims 13-19) in the application. In characterizing the state of the art, the Examiner appears to be making the argument that treating all the claimed conditions and/or diseases with the compounds of Claim 1 suggests an inherently unbelievable undertaking or involves implausible scientific principles. Her basis for this allegation appears to be her assertion that there is no single compound known to treat all disorders from fatty acid metabolism, insulin resistance, diabetes mellitus, dyslipidemia, squelae, and metabolic syndrome diseases. Applicants fail to understand how this fact, if true, is relevant to deny the objective truth of the statements of activity for one or all of the claimed methods of treatment. Therefore, in the absence of a reason supplied by the Examiner to doubt the objective truth of the statements of activity made by Applicant's disclosure, the Patent Office must accept the disclosure of the present application as fully enabling with respect to the claimed methods. Thus, Applicants respectfully submit that the rejection of Claims 13-19 under 35 USC §112, first paragraph for failing to teach how to practice the invention is improper and should be withdrawn.

Conclusion

In view of the amendment and remarks contained herein, Applicants submit the application is in condition for allowance.

Respectfully submitted,

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